

USDA
REGULATORY DOCSUNITED STATES DEPARTMENT OF AGRICULTURE
BEFORE THE SECRETARY OF AGRICULTURE 2003 JUN 27 A. S. 52

In re:)
Nebraska Beef, Ltd,) FMIA Docket No. 03-0002
Respondent.) CONSENT DECISION
) AND ORDER

This is a proceeding under the Federal Meat Inspection Act, as amended (21 U.S.C. § 601 *et seq.*) (FMIA) and the applicable Rules of Practice (7 C.F.R. § 1.130 *et seq.* and 9 C.F.R. Part 500), to withdraw Federal meat inspection services from Nebraska Beef, Ltd., referred to as the respondent herein. This proceeding was commenced by a complaint filed on January 27th, 2003, by the Administrator of the Food Safety and Inspection Service (FSIS), United States Department of Agriculture (USDA), who is responsible for the administration of Federal meat and poultry inspection services. The complaint alleged that Respondent failed to maintain its establishment's conditions or operate in a manner as required by Section 8 of the FMIA (21 U.S.C. §608) and the regulations promulgated thereunder (9 C.F.R. Parts 416 and 417).

The parties have agreed that this proceeding should be terminated by entry of this Consent Decision and Order and have agreed to the following stipulations:

1. For the purpose of this stipulation and the provisions of this Consent Decision and Order only, Respondent admits all jurisdictional allegations of the complaint and waives:
 - (a) Any further procedural steps;

(b) Any requirement that the final decision in this proceeding contain findings and conclusions with respect to all material issues of fact, law or discretion, as well as the reasons or bases thereof; and

(c) All rights to seek judicial review or to otherwise challenge or contest the validity of this decision.

2. This Consent Decision and Order is for settlement purposes in this proceeding only and does not otherwise constitute an admission or denial by Respondent that it violated the statute or regulations involved.

3. Respondent waives any action against the USDA under the Equal Access to Justice Act of 1980 (5 U.S.C. § 504) for fees and other expenses incurred by Respondent in connection with this proceeding.

4. Respondent, its owners, officers, directors, partners, successors, affiliates, and assigns, waive any other action against the USDA, FSIS, or its employees in connection with this proceeding.

5. The parties will stipulate for dismissal without prejudice of the civil proceedings pending in the United States District Court for the District of Nebraska, Nebraska Beef, Ltd. v. United States Department of Agriculture, Case No. 8:03-CV-16, which the respondent and complainant acknowledge will have the effect of terminating the temporary restraining order entered in that action. Nothing in the parties' agreement shall preclude the Respondent from pursuing at a future date any appropriate civil remedy or administrative appeal. Nothing in the parties' agreement shall preclude USDA from pursuing at a future date any available

regulatory, administrative or civil action, or the referral of any matter to any agency for possible criminal, civil or administrative proceedings.

6. The FSIS Technical Service Staff will present written materials on regulatory requirements, responsibilities and inspection methodology within two weeks of the effective date of this Consent Decision and Order. Within thirty (30) days of the effective date of this Consent Decision and Order, the materials will be explained at a joint meeting of FSIS Deputy Administrator of Field Operations, FSIS Circuit Supervisor Ronald Seitz, FSIS District Manager Dennis Greening and other inspection program personnel at the in-plant, circuit, and District levels with the respondent's establishment management, supervisors and employees.
7. FSIS agrees that inspection program personnel will act in accordance with law in carrying out their mandates under the FMIA, and FSIS further agrees that inspection program personnel will carry out their responsibilities in a fair and unbiased manner in accordance with FSIS Directive 4735.3.
8. The parties agree that Appendix A attached hereto will be distributed to plant management officials and FSIS inspection program personnel Nebraska Beef.

Findings of Fact

Nebraska Beef, Ltd. (Respondent), is a recipient of Federal inspection services under the Federal Meat Inspection Act (FMIA) at its Establishment, 19336M, located at 4501 South 36th Street, Omaha, Nebraska 68107.

Conclusion

Because the parties have agreed to the provisions set forth in this Consent Decision in disposition of this proceeding, the following Order will be issued.

ORDER

Inspection services under the FMIA are withdrawn from Respondent, Nebraska Beef, Ltd., its owners, officers, directors, successors, affiliates, or assigns, directly or through any corporate device, for a period of 24 months beginning on the effective date of this Order.

The withdrawal of inspection services shall be held in abeyance, and inspection services shall be provided to Respondent pursuant to a conditional grant of inspection, for so long as, in addition to all other requirements of inspection services, the additional conditions set forth in paragraphs 1-11 below are met:

1. Respondent shall describe the process control systems, procedures and monitoring activities that the Respondent will conduct, implement and maintain, on a daily and on-going basis, before, during and after operations in accordance with 9 C.F.R. Part 416 and 417 to ensure sanitary conditions and to prevent product contamination and adulteration. In particular, Respondent shall assure that monitoring procedures prescribed by Part 416.13 (c) are implemented, shall routinely evaluate the effectiveness of its SSOP and make adjustments to ensure the maintenance of sanitary conditions as required by Part 416.14, and shall take preventive measures as prescribed by Part 416.15 to prevent insanitary conditions and to ensure the production and distribution of wholesome, not adulterated and properly labeled products in commerce.

2. Respondent shall implement, validate, maintain and verify its HACCP system in accordance with the requirements of 9 C.F.R. Part 417 and shall meet all critical limits for CCPs in its HACCP plan in accordance with the requirements of 9 C.F.R. 417.2. Respondent shall implement corrective and preventive actions and reassess its HACCP system, as required by and consistent with 9 C.F.R. Part 417, as necessary to ensure that the regulatory requirements for the control and prevention of pathogens are met and to prevent direct product contamination that presents a public health risk.

3. Respondent's Escherichia coli Biotype I (E. coli) sampling and testing program shall describe the procedures, sampling methodology, frequency, analyses and recording the Respondent will conduct and maintain in order to ensure daily and ongoing compliance with 9 C.F.R. 310.25.

4. Respondent shall collect samples, test for Escherichia coli Biotype I (E. coli), and record and analyze sample results in accordance with 9 C.F.R. 310.25.

5. Respondent shall record and maintain complete and accurate written records of all business activities applicable to the FMIA and the regulations promulgated thereunder, including SSOP and HACCP records. Respondent shall comply with all applicable State and local recordkeeping requirements related to its slaughter and processing business activities. Respondent shall make these records available to FSIS upon request for review and/or copying as required by the FMIA and the regulations promulgated thereunder.

6. Respondent shall not conduct any operation requiring federal inspection outside the official hours of operation with the exception of overtime without obtaining prior approval from FSIS. Respondent shall ensure that all meat and meat food products are properly marked, labeled, and packaged.

7. Respondent, its officers, and/or any other responsibly connected individuals shall not commit any felony or fraudulent act, violate any section of the FMIA, or violate any State or local statute involving the preparation, sale, transportation, or attempted distribution of any adulterated or misbranded meat, poultry or food product or article.

8. Respondent shall designate at least one full-time and one alternate person who shall be responsible for overall implementation, monitoring, verification, validation, reassessment, recordkeeping, review and maintenance of the establishment's sanitation performance standards (SPS), SSOP and HACCP systems, as required by and consistent with 9 C.F.R. Parts 416 and 417. The designated employee(s) shall have completed a course of instruction in the application of HACCP that complies with the requirements of 9 C.F.R. 417.7. Respondent shall maintain documentation of the completion of such training in its establishment and shall make it available to FSIS upon request.

9. Respondent shall, within sixty (60) days from the effective date of this Order, educate each employee in all aspects of food safety measures and regulatory requirements, including the requirements of the SPS, SSOP, HACCP, and E. coli testing relevant to that employee's position. At a minimum, training will be conducted as follows: SPS - all employees; SSOP - employees responsible for sanitation; HACCP - employees responsible for items outlined in the CCP summary. All employees will be provided with a short general class that describes the three programs, and that names the employees responsible under each program. Respondent shall record and maintain written records of the implementation and completion of such training for the duration of the Consent Decision and Order. Respondent shall make these records available to FSIS upon request. Respondent shall make the training materials available for FSIS review upon request. Respondent shall train and educate all new employees, consistent with the requirements of this paragraph, within thirty (30) days of their employment.

Respondent shall conduct on-going training and education of its employees, consistent with the requirements of this paragraph, and maintain records of the implementation and completion of such training.

10. Respondent shall cause to be made, by a qualified, independent third party, written assessments of Respondent's implementation, monitoring and maintenance of its sanitation and food safety control systems, including but not limited to Respondent's compliance with the FSIS sanitation regulations, Respondent's implementation of its SSOP, HACCP system and generic E. coli testing procedures. The written assessment shall include a report of findings and recommendations, if any, of the independent third party. Respondent shall address, in writing, all findings and recommendations of the independent third party. The first assessment will be conducted within sixty (60) days of the effective date of this order. A second assessment will be conducted within ninety (90) days after the first assessment. Additional assessments shall be conducted at each 180 day interval thereafter until the end of the effective date of this Order. Each assessment of the independent third party and Respondent's written response shall be available for review and copying by FSIS within fourteen (14) days after the assessment is completed. Additionally, the independent third party will engage in a monthly review of the establishment's HACCP/SSOP records. Respondent shall name, with the consent of the FSIS, the independent third party responsible for the duties under this paragraph. Provided, however, that the independent third party may not be a former or current employee of Respondent or any affiliated business or entity.

11. Respondent shall fully and completely cooperate with any FSIS investigation, inquiry, review or examination of Respondent's establishment or Respondent's compliance with the FMIA or this Order.

The Administrator, FSIS, may summarily withdraw inspection services from the Respondent upon his determination that the Respondent has failed to meet any critical limit at a critical control point as required in 9 C.F.R. §417.2(c) and has failed to take corrective and preventive action as required in 9 C.F.R. §417.3 and/or has failed to take corrective and preventive action in accordance with 9 C.F.R. §416.¹⁵ for a direct product contamination or adulteration. The Administrator's determination shall be subject to the respondent's right to request an expedited hearing before a USDA Administrative Law Judge to challenge the determination after withdrawal of inspection.

The Administrator, FSIS, shall have the right to withdraw inspection services from the Respondent upon his determination that the Respondent has violated paragraphs 1 through 11 of this Order. The Administrator's determination shall be based upon a final decision in a formal adjudicatory proceeding before a USDA Administrative Law Judge (or upon final affirmation of the Secretary's decision, if appealed.).

The provisions of this Order shall be applicable for a period of 24 months from the date that this Order is issued.

If any provision of this Order is declared invalid, such declaration shall not affect the validity of any other provision herein.

This Order shall become effective upon issuance by the Administrative Law Judge.

John H. Hargan, Jr.

Nebraska Beef, Ltd.

Respondent

William M. Lamson, Jr.

William M. Lamson, Jr.

Attorney for Respondent

Dr. Wm C. Smith, Deputy Administrator, FSIS

Scott C. Safian

Director, Evaluation and Enforcement

Division, FSIS, USDA

Rick Herndon

Rick Herndon

Attorney for Complainant

Issued the 27th day of January, 2003,
at Washington, D.C.

James L. Hart

ADMINISTRATIVE LAW JUDGE

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APPENDIX A

In making decisions regarding compliance to regulatory requirements 416.12(a) and/or 416.2(b)(4), inspection program personnel will keep in mind:

Condensate/condensation is the moisture formed in the air on the surface of an object when the temperature of the object is below the dew point of the air.

Condensation on metal structures often occurs in the environment of meat plants such as cooking in a closed kettle, freeze tunnels, heat-sealing /packaging area, steam/vacuum flush operations and chill tanks.

Plant management officials ensure that the plant is designed and operated in a manner that controls condensation and that does not create an insanitary environment or adulterate product.

Dripping condensation that creates an insanitary environment or adulterates product is prohibited.

Some forms of condensation pose no risk of adulterating product under certain conditions such as on surfaces that are cleaned and sanitized as defined and determined effective in the SSOP.

Carcasses, organs and other parts shall be handled in a sanitary manner to prevent contamination with fecal material, urine, bile, hair, dirt, or foreign matter; however, if contamination occurs, it shall be promptly removed in a manner satisfactory to the inspector (310.18(a)). Lactating mammary glands and diseased mammary glands of cattle shall be removed without opening the milk ducts or sinuses. If pus or other objectionable material is permitted to come in contact with the carcass, the parts of the carcass thus contaminated shall be removed and condemned (310.17(a)). Inspection personnel (on-line and off-line) verify these regulatory requirements utilizing FSIS Directive 6420.1.

A critical limit failure will not result in a summary withdrawal or suspension of inspection when the company complies with 417.3(a). That is

The cause of the deviation is identified and eliminated;

The CCP will be under control after the corrective action is taken;

Measures to prevent recurrence are established; and

No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

Nebraska Beef's use of 180 degree water is covered under the Background section of FSIS Directive 11,000.1, issued 1/25/00, which states---It is important to note that establishments that met the relevant sanitation requirements before promulgation of the

rule do not have to do anything differently to continue to remain in compliance now that the rule (SPS) has been published.